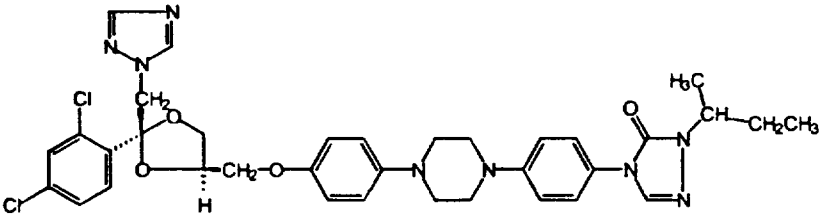


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

**20-966/S-001, S-003, S-004
20-657/S-004, S-005**

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW				1. ORGANIZATION: HFD-590		2. NDA NUMBER: 20-966	
3. NAME AND ADDRESS OF APPLICANT: (City and State) Janssen Research Foundation 1125 Trenton-Harbourton Road Titusville, NJ 08560				4. AF NUMBER:			
				5. SUPPLEMENT(S):			
				NUMBER(S): SE1-004 SE1-004/BZ		DATE(S): April 28, 2000 July 28, 2000	
6. NAME OF DRUG: Sporanox® Injection				7. NONPROPRIETARY NAME: Itraconazole			
8. SUPPLEMENT PROVIDES FOR: empiric therapy in febrile neutropenic patients with suspected fungal infections.				9. AMENDMENTS/REPORTS:			
10. PHARMACOLOGICAL CATEGORY: Antifungal		11. HOW DISPENSED: [X] Rx [] OTC		12. RELATED IND/NDA/DMF(S): NDA 20-083, 20-657			
13. DOSAGE FORM(S): Injection				14. POTENCY(IES): 10 mg/mL			
15. CHEMICAL NAME AND STRUCTURE: 4-[4-[4-[[2-(2,4-Dichlorophenyl)-2-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxyphenyl]-1-piperazinyl]phenyl]-2,4-dihydro-2-(1-methylpropyl)-3 <i>H</i> -1,2,4-triazol-3-one CAS: 84625-61-6 				16. MEMORANDA:			
17. COMMENTS: The applicant has claimed a categorical exclusion from Environmental Assessment since the Expected Introduction Concentration (EIC) of itraconazole into the aquatic environment is estimated to be less than 1 ppb. Janssen certifies that no extraordinary circumstances exist.							
18. CONCLUSIONS AND RECOMMENDATIONS: The sponsor has met the requirements for a categorical exclusion under 21 CFR § 25.31 (b). This supplement may be approved from a CMC perspective.							
19. REVIEWER: Gene W. Holbert, Ph.D.		SIGNATURE:		DATE COMPLETED:			
20. CONCURRENCE: Norman R. Schmuff, Ph.D.							
DISTRIBUTION:	X	Original: NDA 20-966	X	HFD-590: N.Schmuff	X	HFD-590: L.Kimzey	
	X	Division File HFD-590	X	HFD-590: G.Holbert	X	HFD-830: C.Chen	